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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,725	08/01/2003	David E. Wolf	205-007US2	2807

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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT PAPER NUMBER

1639

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/632,725	<b>Applicant(s)</b> WOLF ET AL.	
	<b>Examiner</b> Mark L. Shibuya	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 6/9/2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-117 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-117 are pending.

#### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-58, drawn to methods of assaying for the equilibrium interaction of a probe and an unknown target, classifiable in class 435, subclass 7.1.
  - II. Claims 59-69, drawn to methods for assaying for the presence of a pathogen in a sample, classifiable in class 435, subclass 35.
  - III. Claims 70-73, drawn to methods for assaying for the presence of a toxin in a sample, classifiable in class 435, subclass 71.3.
  - IV. Claim 74, drawn to a method of identifying a probe capable of binding to a known pathogen, classifiable in class 435, subclass 7.2.
  - V. Claims 75-78, drawn to a kit comprising a first probe, which comprises fluorescently tagged ricin, and that is bound to a second probe, which is adapted to bind ricin, classifiable in class 435, subclass 9.6.
  - VI. Claims 79-86, drawn to a method for assaying for the presence of molecular interactions of a probe and a target, comprising a plurality of unique mass adding components each unique mass adding component having a unique mass, classifiable in class 435, subclass 4.

- VII. Claims 87-91, drawn to a kit comprising a plurality of unique beads, each unique bead having a different size and attached to a plurality of probes, which bind to a unique target, and a plurality of fluorescent tags, classifiable in class 436, subclass 523.
- VIII. Claims 92-100, drawn to methods of determining a true correlation or autocorrelation function of a sample, comprising obtaining a first measured autocorrelation function of the sample from a first detector of a fluorescence correlation spectroscopy, obtaining a second measured autocorrelation function of the sample from a second detector of the instrument, obtaining a measured crosscorrelation function between the first detector and the second detector of the instrument, and determining the true autocorrelation function of the fluorescence measured at the first detector, classifiable in class 436, subclass 517.
- IX. Claims 101-107, 108, 115-117, drawn to an article of manufacture comprising a computer readable medium having stored therein a computer program for determining a true correlation function of a sample, and a fluorescence correlation spectroscopy instrument for determining a true correlation function of a sample comprising a programmed processor, classifiable in class 702, subclass 23.
- X. Claims 109-114, drawn to a method of determining a true fluorescence intensity of a sample, comprising obtaining a first fluorescence intensity of the sample from a first detector of a fluorescence correlation spectroscopy

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and applying a correctional algorithm, classifiable in class 436, subclass 546.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-IV, VI, VIII, and X are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are drawn to assaying for equilibrium interaction, assaying for the presence of a pathogen, assaying for the presence of a toxin, identifying a probe capable of binding to a known pathogen, assaying for the presences of molecular interactions comprising a plurality of unique mass adding components, determining a true correlation or autocorrelation function of a sample, and determining a true fluorescence intensity of a sample, have different modes of operation, function or effects.

The Inventions of Groups V, VII, and IX are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the kits comprising fluorescently tagged ricin, kits comprising a plurality of

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unique beads attached to a plurality of probes, an article of manufacture comprising a computer readable medium having a computer program and a fluorescence correlation spectroscopy instrument for determining a true correlation function of a sample, have different modes of operation, function or effects.

The Inventions of Group V and the Inventions of Groups I-IV, VI, VIII, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product may be used to deliver ricin-conjugated immunotoxins to cells.

The Inventions of Group VII and the Inventions of Groups I-IV, VI, VIII, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product may be used to immobilize targets for isolation and purification.

The Inventions of Group IX and the Inventions of Groups I-IV, VI, VIII, and X are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used

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to practice another and materially different process. (MPEP § 806.05(e)). In this case the process may be practiced without another and materially different apparatus that does not comprise a computer readable medium having a computer program stored therein.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

### ***Election of Species***

3. This application contains claims directed to the following patentably distinct species: Methods comprising (a) one probe; or (b) two or more probes. The species are independent or distinct because they have different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 52, 59, 60, 70, 74 are generic.

4. This application contains claims directed to the following patentably distinct species: Applicant must elect one species of probe. The species are independent or

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distinct because different probes have different molecular core structures that are responsible for their different properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 52, 59, 60, 70, 74, 75, 79, 87 are generic.

5. This application contains claims directed to the following patentably distinct species: Applicant must elect one species member of a library. The species are independent or distinct because the different members have different molecular structures conferring different properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 7, 8-14, 36, 52, 59, 60, 70, 74, 75, 79, 87, 92, 98 are generic.

6. This application contains claims directed to the following patentably distinct species: Applicant must elect one species of fluorescent tag. The species are independent or distinct because the different fluorescent tags have different molecular structures and different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

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finally held to be allowable. Currently, 1, 27, 28, 38-42, 45, 46, 48, 52-55, 59, 60, 70, 72, 73, 74, 75, 77, 78, 79-82, 84-86, 87, 88, 90, 91 are generic.

7. This application contains claims directed to the following patentably distinct species: Applicant must a method of creating a unique site. The species are independent or distinct because they have different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 19-24 are generic generic.

8. This application contains claims directed to the following patentably distinct species: Applicant must elect a species of unique site. The species are independent or distinct because they have different molecular structures.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 19-24 are generic.

9. This application contains claims directed to the following patentably distinct species: Applicant must select a method wherein a probe and member are (a) attached to a bead or (b) not attached to a bead. The species are independent or distinct because the methods have different modes of action.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 52, 59, 60, 70, 74, 75, 79, 87 are generic.

10. This application contains claims directed to the following patentably distinct species: A method wherein the fluorescent tag is attached to (a) a member of a library or (b) a probe. The species are independent or distinct because the methods have different modes of action.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 27, 28, 38-42, 45, 46, 48, 52-55, 59, 60, 70, 72, 73, 74, 75, 77, 78, 79-82, 84-86, 87, 88, 90, 91 are generic.

11. This application contains claims directed to the following patentably distinct species: Analyzing comprising at least one of moment analysis, Fourier transform analysis or power spectrum analysis. The species are independent or distinct because the different analyses have different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 33 are generic.

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12. This application contains claims directed to the following patentably distinct species: A method wherein the fluorescent tag is attached to (a) a member of a library or (b) a unknown target. The species are independent or distinct because methods have different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 52 is generic.

13. This application contains claims directed to the following patentably distinct species: A pathogen component comprising a bacterium, virus, pathogen, pathogen fragment, pathogen nucleic acid, pathogen protein, pathogen carbohydrate, combinations thereof (specify), pathogen spore, pathogen toxin, metabolic product of pathogen, combinations thereof (specify). The species are independent or distinct because the different pathogen components have different molecular structures that result in different properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 60, 65-69 are generic.

14. This application contains claims directed to the following patentably distinct species: A method wherein the fluorescent tag is attached to (a) a mass adding

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component; (b) a probe; or (c) targets.. The species are independent or distinct because the methods have different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 79-86 are generic.

15. This application contains claims directed to the following patentably distinct species: A method wherein a sample comprises (a) at least a portion of the members of a library; (b) a pathogen; (c) a toxin; or (d) a combination thereof (specify). The species are independent or distinct because they have different molecular core structures that confer different properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 92, 98 are generic.

16. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations

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of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

17. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Shibuya  
Examiner  
Art Unit 1639

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